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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,364	10/22/2003	Aaron H. Shovers	S006-P03038US	9385

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EXAMINER	
SCHLIENTZ, LEAH H	
ART UNIT	**PAPER NUMBER**
1618	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/692,364	SHOVERS ET AL.	
	Examiner	Art Unit	
	Leah Schlientz	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,11-18,20-24 and 26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9, 11-18, 20-24, and 26* is/are rejected.

7)☒ Claim(s) *16-18 and 20-23* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments and amendments, filed 12/7/06, have been entered. Claims 1, 2, 8, 16, and 24 have been amended, and claims 10, 19, and 25 have been cancelled. Claims 1 – 9, 11 – 18, 20 – 24, and 26 are pending.

Applicant's arguments filed 12/7/06 have been fully considered but they are not persuasive. Applicant amended independent claims 1, 16, and 24 to include the limitation "wherein the monitoring material is a material selected from the group comprising a naturally weak organism, an attenuated virus, a fungus and a bacteria, wherein the material is tagged with a color," and asserts that the rejection of claims 1 – 9, 11 – 18, 20 – 24, and 26 under 35 USC 112, first paragraph, as failing to comply with the written description requirement has been overcome by said amendment. This is not found persuasive because applicant has only partially addressed the reasons for rejection set forth in the Office Action mailed 6/30/06. The rejection of claims 1 – 9, 11 – 18, 20 – 24, and 26 under 35 USC 112, first paragraph, as failing to comply with the written description requirement has been maintained because the claimed subject matter was not described in the specification in such a way to reasonably convey to one skilled in the art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as set forth herein below.

Any other rejections not reiterated herein have been withdrawn as having been overcome by amendment.

Claim Objections

Claim16 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 1. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Similarly, claim 17 is objected to on the basis of being a substantial duplicate of claim 7, claim 18 is objected to on the basis of being a substantial duplicate of claim 9, claim 20 is objected to on the basis of being a substantial duplicate of claim 11, claim 21 is objected to on the basis of being a substantial duplicate of claim 12, claim 22 is objected to on the basis of being a substantial duplicate of claim 13, and claim 23 is objected to on the basis of being a substantial duplicate of claim 14.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 - 9, 11 - 18, 20 - 24, and 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The invention is drawn

to a method of monitoring a condition of an animal, the animal having a visually observable tissue comprising selecting a monitoring material for introduction into the animal, wherein the monitoring material is a material selected from the group comprising a naturally weak organism, an attenuated virus, a fungus, and a bacteria, wherein the material is tagged with a color. The material is introduced into the animal at selected sites, wherein introducing the monitoring material is effected by a process selected from the group comprising injecting under the skin, implantation, and transplantation. A visually ascertainable indication, wherein the monitoring is not diagnosing, is monitored and observed to thereby visually ascertain the status of the condition. The visually ascertainable indication is a reversible change in color of the monitoring material.

The specification fails to provide the requisite description to practice the very broad and generic monitoring method. There are an almost unlimited number of "conditions" of an animal body, and the specification discloses a wide variety of extremely diverse conditions to include immunity, the ability to produce antibodies, the general condition of an animal, hormone levels, temperature, exposure to radiation, lack of sleep, mental stress, the presence of certain levels of proteins, microbes, toxins, etc. (paragraph 22 – 25). The monitoring material may also include a very diverse number of materials. The limitation of the presently amended claims (i.e. wherein the monitoring material is selected from the group *comprising* a naturally weak organism, attenuated virus, etc.) is open-ended because of the comprising language within the Markush group, and essentially provides no limitations as to the identity of a monitoring material,

as broadly claimed, other than that a monitoring material is tagged with a color. There are an almost unlimited number of species which may represent such a monitoring material (i.e. a multitude of species may be represented by organisms, viruses, bacteria, various organic material, etc) (paragraph 26). There is no description provided regarding which specific monitoring materials is to be selected out of a very large and diverse number of potential materials which is used to monitor which specific condition out of a very large and diverse number of potential conditions. There are no chemical or biological structures or identities provided to represent any specific monitoring material. Because the structures and physical identities of these elements are undefined, it is unclear how Applicant envisaged any specific combination of which material would be capable of achieving a monitoring function of which specific condition. Because of the inherent unpredictability of *in vivo* methods, it is essential that a certain degree of guidance is provided to specify what materials are used to monitor what conditions. For example, it is unclear (or even unlikely) how a fungus tagged with a color, for example, to represent a monitoring material, when injected into the skin would be capable of monitoring exposure to radiation, for example, to represent a condition. As another example, it is unclear and quite unlikely that a bacteria tagged with a color, for example, to represent a monitoring material, when implanted into a tooth, for example, to represent a site on an animal, would be capable of monitoring lack of sleep, for example, as a condition to be monitored. Furthermore, the specification does not describe any embodiments of any specific combination of monitoring material and condition to be monitored to show that describe a process for actually practicing the

broadly claimed monitoring method. There are no working examples to demonstrate that the invention as claimed may be successfully reduced to practice. Because of the wide variety of chemical or biological moieties which may represent monitoring materials and the wide variety of conditions which may be monitored, a more detailed description of what is being claimed is necessary to show possession of the invention. For example, a *specific material* that can be used to monitor a *specific condition* should be described, as well as how the monitoring takes place. In sum, the specification does not provide any description of the specifics of the steps required to practice the very broad and generic monitoring method as claimed.

Claims 1 - 9, 11 - 18, 20 - 24, and 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification, as originally filed, does not recite that the method of monitoring a condition of an animal includes the step of monitoring the visually ascertainable indication, wherein the monitoring is "not diagnosing." This is a new matter rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 - 9, 11 - 18, 20 - 24, and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The limitations of independent claims 1, 16, and 24, "wherein the monitoring material is a material selected from the group *comprising* a naturally weak organism, an attenuated virus, a fungus, and a bacteria," or "wherein introducing the monitoring material is effected by a process selected from the group *comprising* injecting under the skin, implantation, and transplantation" are open-ended, and as such do not impose *any* limitations on the claimed monitoring material or the method of introducing the monitoring material. Attention is directed to MPEP 2173.05(h). Alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. One acceptable form of alternative expression, which is commonly referred to as a Markush group, recites members as being "selected from the group consisting of A, B and C." See *Ex parte Markush*, 1925 C.D. 126 (Comm'r Pat. 1925). *Ex parte Markush* sanctions claiming a genus expressed as a group consisting of certain specified materials. It is improper to use the term "comprising" instead of "consisting of" in a Markush group within a claim. *Ex parte Dotter*, 12 USPQ 382 (Bd. App. 1931).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 7 – 9, 12 – 18, 21 – 24, and 26 are rejected under 35 USC 102(e) as being anticipated by Gratzl *et al.* (US 2004/0180391).

Gratzl discloses *in vivo* monitoring of chemical and biochemical species (e.g. pH or glucose levels) (i.e. a condition) in the interstitial fluid of patients by a probe (i.e. a monitoring material). The probe is readily inserted by a minimally invasive method. Optical or electrochemical methods are employed to detect a physical or chemical change, such as pH, color, etc., which is indicative of the concentration of the species or chemical which is to be detected. Visual observation by the patient may be sufficient to monitor certain biochemicals (e.g. glucose) (abstract). The invention finds particular application in monitoring of glucose in diabetics (i.e. a condition) (paragraph 0003). According to the methods disclosed by Gratzl, a sensor probe for detection of an analyte in solution is provided. The probe includes a sensing element which exhibits a detectable change in response to the analyte. The sensing element includes an immobilized optical sensing system including an enzyme capable of catalyzing a reaction of the analyte to from a reaction product, an ionophore which extracts an ion

from the reaction product, and a chromoionophore sensitive to the ion which exhibits a detectable color change in response to the ion. The enzyme is immobilized on a support material, which may include cellulose acetate phthalate. A dye system exhibits a color change in response to the reaction product (paragraphs 0009 – 0013). The probe is preferentially implanted beneath the person's skin or other body tissue, for example by syringe needle, piston, or other implantation device. The probe can be easily inserted through the epidermis into the subcutaneous tissue below (paragraph 0067). The probe can be operated automatically, e.g. by using a detection of a color change or other detectable chemical of physical property (paragraph 0078). In one embodiment, the invention uses optical detection (i.e. visually ascertainable). The color of the probe changes with changing concentration of an analyte (i.e. glucose). The probe, implanted beneath the skin of the person, includes one or more sensing elements (paragraph 0088). Each sensing element generally includes an indicator material, such as pH sensitive dye which undergoes a chemical of physical change in response to the analyte to be detected (paragraph 0098). An exemplary dye is one which is sensitive to hydrogen ions (pH) and which is reversible (i.e. returns to its previous color when pH returns to its previous level). A preferred pH sensitive dye preferably includes an ionophore, a lipophilic anion, and a lipophilic hydrogen ion sensitve dye, also referred to as a chromoionophore, as it changes color. Exemplary chromoionophores may be specifically 9-(diethylamino)-5-(octadecanoylimino)-5H-benzo[a]phenoxazine, etc. (paragraphs 0101 – 0103). The human eye can function as a detector since the color change is readily detectable through the skin. For example, a

diabetic patient may be instructed that a change from green to orange is an indication that the blood sugar is too high (paragraph 0135). In the case of glucose detection, the conversion of glucose (a neutral molecule) to gluconic acid results in a pH change (paragraph 0210). The probe is especially effective for glucose measurements based on a suitable enzyme such as glucose oxidase (GOX) (paragraph 0251). Regarding claim 15, the order in which the steps are performed does not constitute a functional limitation of the claimed invention over those evidenced by Gratzl. Regarding claims 1 (and 16), wherein "the monitoring material is a material selected from the group *comprising* a naturally weak organism, an attenuated virus, a fungus and a bacteria, wherein the monitoring material is tagged with a color," the comprising language within a Markush group is open-ended and results in essentially *no* limitations on the identity of the monitoring material, other than that the material is tagged with a color. Regarding the limitations of claim 24, wherein the condition has a normal status, and if the condition has changed from normal multiple appearances are visualized depending upon a change from normal, the methods of Gratzl may detect absorbance in a wavelength range corresponding to the protonated form of the chromoionophore, changes in the concentration of e.g. glucose can be observed using a calibration curve (i.e. multiple observances) (paragraph 0130).

Claims 1, 2, 8, 9, 11 – 18, 20 – 23, and 26 are rejected under 35 USC 102(b) as being anticipated by Friars *et al.* (US 6,290,977).

Friars discloses a topical flowable personal care product, and more specifically, a shower gel shampoo, body lotion, moisturizing cream, sunscreen, skin toner, or the like, exhibiting a thermochromic color change, preferably at a discrete temperature, preferably at a temperature between about 20 °C (room temperature) and about 37 °C. (skin or shower-water temperature). The composition thus changes in response to body heat or the heat of a bath or shower (abstract). The pigments in the thermochomic lotion may be reversible (column 2, line 1), and includes a (visibly observable) color change (i.e. from blue to white, depending on temperature (i.e. "a condition") (column 9, line 29). The lotion may be used to tell (i.e. by observation of color) if persons exposed to cold weather have an unsatisfactorily low body temperature (column 9, lines 46+). In another example, when determining the effectiveness of cold-weather clothing it is necessary to *monitor* the temperature of the skin of the subject being tested, which is difficult to do with thermometers, and is another application of the disclosed lotion (column 10, lines 10 – 14). The lotion gives a display which can immediately and easily by optically (i.e. visibly) recognized (column 10, line 21). Regarding claims 1 (and 16), wherein "the monitoring material is a material selected from the group *comprising* a naturally weak organism, an attenuated virus, a fungus and a bacteria, wherein the monitoring material is tagged with a color," the comprising language within a Markush group is open-ended and results in essentially *no* limitations on the identity of the monitoring material, other than that the material is tagged with a color. Similarly, regarding the limitations wherein "introducing the monitoring material is effected by a process selected from the group *comprising* injecting under the skin, implantation, and

transplantation," the comprising language within a Markush group is open-ended and results in essentially *no* limitations on the introducing step.

Claims 1, 2, 4, 5, 7 – 9, 12, 13, 15 – 18, 21, 22, and 26 are rejected under 35 USC 102(b) as being anticipated by Bender (US 2,151,495) for reasons set forth in the Office Action mailed 6/30/06.

Regarding currently amended claims 1 (and 16), wherein "the monitoring material is a material selected from the group *comprising* a naturally weak organism, an attenuated virus, a fungus and a bacteria, wherein the monitoring material is tagged with a color," the comprising language within a Markush group is open-ended and results in essentially *no* limitations on the identity of the monitoring material, other than that the material is tagged with a color. Similarly, regarding the limitations wherein "introducing the monitoring material is effected by a process selected from the group *comprising* injecting under the skin, implantation, and transplantation," the comprising language within a Markush group is open-ended and results in essentially *no* limitations on the introducing step. The disclosing solution taught by Bender contains Guinea Green B and/or Rose Bengal which is applied to teeth and renders visible bacterial plaques by forming temporary (i.e. reversible) stains on the plaque on the teeth (see paragraph 1, lines 1 – 9, paragraph 8, lines 51 – 55, and claims 1 – 7). Applicant's argument that Bender does not disclose the claimed observing the visually ascertainable indication has been fully considered but is not found persuasive. Bender teaches that dental plaques are not readily visible unless treated with a disclosing

solution (column 1, line 6). Accordingly, the entire purpose of the disclosing solution taught by Bender is to render plaques (i.e. a condition) visible (i.e. observable) with a coloring material.

Claims 1, 2, 4 – 9, 12, 13, 15 – 18, 21, 22, and 26 are rejected under 35 USC 102(e) as being anticipated by Ribi (US 6,607,744).

Ribi discloses methods and compositions comprising ingestibles and a thermochromic composition which is informative as to the temperature history of the ingestible, either prior or contemporaneous with use. Various solid or liquid ingestible compositions are provided for determining storage temperature, temperature of the user (i.e. a condition) (etc.). Of particular interest are polydiacetylene polymers which may be formulated to provide compositions having transition temperature over a broad temperature range (abstract). Reversible color changes are important for ingestible applications where the injestible undergoes a temperature transition from one level to another and then back to the original temperature and it is desirable to use the color changes to communicate to the observer characteristics about the injestible (column 5, lines 32 – 36). For example, the chromic material may be in a mouthwash which changes color (i.e. a visible observable) if a user has a fever, which would inherently be present inside the mouth, i.e. on a cheek (column 22, lines 11 – 12). Regarding claims 1 (and 16), wherein "the monitoring material is a material selected from the group *comprising* a naturally weak organism, an attenuated virus, a fungus and a bacteria, wherein the monitoring material is tagged with a color," the comprising language within

a Markush group is open-ended and results in essentially *no* limitations on the identity of the monitoring material, other than that the material is tagged with a color. Similarly, regarding the limitations wherein "introducing the monitoring material is effected by a process selected from the group *comprising* injecting under the skin, implantation, and transplantation," the comprising language within a Markush group is open-ended and results in essentially *no* limitations on the introducing step.

Conclusion

No claims are allowed at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leah Schlientz whose telephone number is 571-272-

9928. The examiner can normally be reached on Monday - Friday 8 AM - 5 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LHS

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER